

REMARKS

This Letter and Response to Final Rejection is respectfully submitted in order to transmit copies of the Request for Continued Examination, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references filed on March 25, 2005, as well as a newly-executed RCE and Petition for Extension of Time. A Sixth IDS, Form PTO-1449 and reference is also enclosed.

An Office Action rejecting the Request for Examination (RCE) was rendered on April 6, 2005 as not being accompanied by a submission as required by 37 CFR 1.114. As the attachments indicate, several papers made up the submission under 37 CFR 1.114, however upon inquiry applicants were informed that reference to the Final Rejection was not made on page 1 of the Letter and Amendment filed on March 25, 2005. Notwithstanding, applicants respectfully submit that they referred to the Final Rejection on page 6 of the Letter and Amendment filed on March 25, 2005 under "Remarks" and that there was a sufficient submission to meet the requirements of 37 CFR 1.114. In addition, applicants filed an Information Disclosure Statement accompanying the RCE, which also would have fulfilled the requirements of 37 CFR 1.114. Applicants respectfully submit that the RCE met the requirements of 37 CFR 1.114 and was timely filed in conjunction with the previous Petition for Extension of Time. Thus, applicants should **not** be charged for any additional time extensions. However, in an abundance of caution, applicants are submitting herewith an additional Petition for Extension of Time and an additional RCE.

Applicants respectfully amend the Specification of the above-captioned patent application in order to correct the claim of benefit of priority to Provisional Patent Application No. 60/069,797 filed December 16, 1997. This claim of priority was inadvertently omitted in the original Declaration and was only discovered upon recent review of the application file. Applicants also respectfully submit herewith a Supplemental Declaration which both reflects the proper inventorship and amends the Declaration to reflect the relationship between the above-identified patent application and Provisional Patent Application No. 60/069,797, filed December 16, 1997, which was

inadvertently omitted from the original declaration. Applicants respectfully request that the claim of the benefit of priority from Provisional Patent Application No. 60/069,797 be granted.

Applicants also respectfully submit that the inventorship of the above-identified patent application inadvertently omitted Dr. Michael Costanzo when the application was originally filed. The remaining inventors are in agreement with adding Dr. Costanzo to the inventorship, as evidenced by the attached Petition to Change Inventorship and Supplemental Declaration.

The Final Rejection of October 25, 2004 rejected claims 24 and 28-35 under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. Claims 24, 28-36, 38, 40, 44-47 and 58 were further rejected under 35 U.S.C. 102(b) as being anticipated by Kosaka and JP 62036304 (Katsumi).

Applicants respectfully request reconsideration of the above-mentioned rejections under 35 U.S.C. 102 and 103(a) in light of the foregoing amendments to the claims and the ensuing discussion.

The Final Rejection rendered October 25, 2004 objects to applicants' distinction between the claimed method set forth in claims 24, 28-36, 28, 40, 44-47 and 58 and Limkatrul et al., Kosaka and Katsumi. As has been noted on several occasions during the course of the prosecution of the above-captioned patent application, soy products containing soy trypsin inhibitor activity were well-known to be dangerous for human ingestion. [See Declaration of Katharine Martin filed March 7, 2002] Soy products containing such activity can cause, for example, gastric distress [Martin Declaration, ¶4], morphological alterations of small intestinal epithelium in calves [Martin Declaration, ¶5] and pancreatic enlargement [Martin Declaration, ¶5].

Thus, whether or not Limkatrul et al., Kosaka or Katsumi indicated that the soybean milk protein administered to the mice in Limkatrul's study contained soy trypsin inhibitory activity, those of ordinary skill in the art would not have expected to be able to administer soybean milk protein containing soy trypsin inhibitory activity to a human being.

Furthermore, Kosaka neither suggests nor describes the claimed method of using soy products. Kosaka merely refers to the use of papain, an enzyme found in papaya, in combination with citric acid, for therapeutic effects on diseases of the circulatory and digestive systems. Kosaka does not teach or suggest topical formulations or applications nor does it

recognize the use of soy products for phagocytosis. The Final Rejection states, with respect to Kosaka, that "...it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk." [Final Rejection, p.3] While applicants recognize that tofu is eaten as a food source, tofu is another soy product that is **processed and cooked prior to eating** such that the soy trypsin inhibitory activity is removed from the food. Soybean milk that is intended for human consumption is also processed to remove the dangerous STI activity prior to ingestion. These soy products are distinguishable from the compositions and methods of applicants' invention which **do** contain soy trypsin inhibitory activity. Thus, Kosaka neither suggests nor describes the methods of applicants' invention.

While Katsumi refers to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere does it suggest or describe the use of non-denatured soy products containing soy trypsin inhibitory activity for increasing or decreasing phagocytosis.

Applicants therefore respectfully request reconsideration of the rejections of claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102 as being anticipated by Limkatrul et al., Kosaka and Katsumi and under 35 U.S.C 103 in view of Limkatrul taken with Kosaka or Katsumi.

The Final Rejection further rejected claims 24, 28-36, 38, 40, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110/409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections.

Applicants respectfully request correction of the claim of the benefit of priority with respect to the abovementioned provisional patent application, addition of Michael Costanzo to the inventorship of the above-captioned patent application and

reconsideration of the rejections set forth in the Final Rejection of October 25, 2004. An early allowance is earnestly solicited.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and
Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

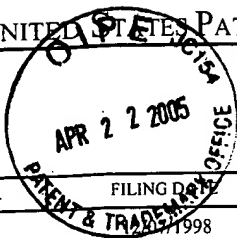
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
Dated: April 22, 2005



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/206,249	7590 04/06/2005	MIRI SEIBERG	JBP438	5255

PHILIP S. JOHNSON, ESQ.
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 04/06/2005

Response Due 4/28/05

Please find below and/or attached an Office communication concerning this application or proceeding.

RECEIVED

APR 11 2005

J&J PAT. DKT. SECTION



APPLICATION NUMBER FILING DATE

FIRST NAMED APPLICANT

ATTY. DOCKET NO./TITLE

DATE MAILED:

NOTICE OF IMPROPER REQUEST FOR CONTINUED EXAMINATION (RCE)

The request for continued examination (RCE) under 37 CFR 1.114 filed on 03.28.05 is improper for reason(s) indicated below:

- ☐ 1. Continued examination under 37 CFR 1.114 does not apply to an application for a design patent. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b) or a CPA under 37 CFR 1.53(d).
- ☐ 2. Continued examination under 37 CFR 1.114 does not apply to an application that was filed before June 8, 1995. Applicant may wish to consider filing a continuing application under 37 CFR 1.53(b) or a CPA under 37 CFR 1.53(d).
- ☐ 3. Continued examination under 37 CFR 1.114 does not apply to an application unless prosecution in the application is closed. If the RCE was accompanied by a reply to a non-final Office action, the reply will be entered and considered under 37 CFR 1.111. If the RCE was not accompanied by a reply, the time period set forth in the last Office action continues to run from the mailing date of that action.
- ☐ 4. The request was not filed before payment of the issue fee, and no petition under 37 CFR 1.313 was granted. If this application has not yet issued as a patent, applicant may wish to consider filing either a petition under 37 CFR 1.313 to withdraw this application from issue, or a continuing application under 37 CFR 1.53(b).
- ☐ 5. The request was not filed before abandonment of the application. The application was abandoned, or proceedings terminated on _____. Applicant may wish to consider filing a petition under 37 CFR 1.137 to revive this abandoned application.
- ☐ 6. The request was not accompanied by the fee set forth in 37 CFR 1.17(e) as required by 37 CFR 1.114. Since the application is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.
- ☒ 7. The request was not accompanied by a submission as required by 37 CFR 1.114. Since the application is not under appeal, the time period set forth in the final Office action or notice of allowance continues to run from the mailing date of that action or notice.

Note: If a request for a continued prosecution application (CPA) under 37 CFR 1.53(d) has been filed in the utility or plant application (including a previously filed CPA) that was filed on or after May 29, 2000, the request for a CPA has been treated as a RCE because the CPA practice no longer applies to such application. The constructive RCE, however, is improper for reason(s) indicated above.

A copy of this notice MUST be returned with any reply.

Direct the reply and any questions about this notice to:

Grega N. Duckett, Examining Group 1600
571-272-0522
(703)60

Serial No. 09/206,249 Docket No. JP-438 By ALC
Application of Seiberg et al. Mailed March 25, 2005
Entitled Compositions and Methods for Regulating Phagocytosis
and ICAM-1 Expression

THE FOLLOWING HAS BEEN RECEIVED IN THE U.S. PATENT OFFICE ON THE DATE STAMPED HEREON:

☐ Provisional ☐ Nonprovisional ☐ CPA ☒ RCE ☐ CIP ☐ Divisional ☐ Design ☐ PCT
☐ Continuation ☐ Other

☒ Petition, Amendment, Statement of Assignee and Fee to Correct
☒ Oath or Declaration Inventorship Express Mail Certificate
☒ Statement of Facts
☐ Assignment

☐ Fee Transmittal

☒ Charge to Deposit Account 10-0750

☐ Priority Document

☐ Data Sheet

☒ IDS-Form 1449 w/ Refs & Fifth Supplemental
IDS

☒ Extension of Time

☐ PTO 1390 (PCT)

☐ # _____

☐ Specification _____ pgs

☐ Claims _____

☐ Drawings _____ sheets

☐ Preliminary Amendment

☐ Sequence Listings/Diskette

☐ Biological Deposit Declaration

☒ Other Transmittal Letter &
Amendment

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

**REQUEST
FOR
CONTINUED EXAMINATION
(RCE)
TRANSMITTAL**

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000,
provides for continued examination of an utility or plant application
filed on or after June 8, 1995.
See The American Inventors Protection Act of 1999 (AIPA).

Application Number	09/206,249
Filing Date	December 7, 1998
First Named Inventor	Seiberg et al.
Group Art Unit	1654
Examiner Name	M. Meller
Attorney Docket Number	JBP-438

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.

NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See *Changes to Application Examination and Provisional Application Practice*, Final Rule, 65 Fed. Reg. 50092 (Aug. 16, 2000); Interim Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.

1. Submission required under 37 C.F.R. § 1.114

- a. ☐ Previously submitted
- i. ☐ Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on
(any unentered amendment(s) referred to above will be entered).
- ii. ☐ Consider the arguments in the Appeal Brief or Reply Brief previously filed on
- iii. ☐ Other
- b. ☒ Enclosed
- i. ☒ Amendment/Reply
- ii. ☒ Affidavit(s)/Declaration(s)
- iii. ☒ Information Disclosure Statement (IDS)
- iv. ☒ Other Form 1449 with copies of references
- v. ☒ Petition To Correct Inventorship

2. Miscellaneous

- a. ☐ Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required.)
- b. ☐ Other

3. Fees - The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed

- a. ☒ The Director is hereby authorized to charge the following fees, or credit any overpayments, to Deposit Account No. **10-0750/JPB438/ALC.**
- i. ☒ RCE fee is required under 37 C.F.R. § 1.17(e)
- ii. ☒ Extension of Time (37 C.F.R. §§ 1.136 and 1.17)
- iii. ☐ Other
- b. ☐ Check in the amount of \$_____ enclosed
- c. ☐ Payment by credit card (Form PTO-2038 enclosed)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

Name (print/type)	Andrea L. Colby	Registration No.	30,194
Signature	/Andrea L. Colby/	Date	March 25, 2005

CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner For Patents, Washington, DC 20231, or facsimile transmitted to the U.S. Patent and Trademark Office on:

Name (print/type)	Andrea L. Colby - Reg. No. 30,194	Date	March 25, 2005
Signature	/Andrea L. Colby/	Date	March 25, 2005

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REQUEST FOR CONTINUED EXAMINATION (RCE) TRANSMITTAL

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Examiner Name	M. Meller
Attorney Docket Number	JBP-438

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Signature	/Andrea L. Colby/	Date	March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miri Seiberg, et al.

Serial No.: 09/206,249 Art Unit: 1651

Filed : July 6, 1998 Examiner: M. Meller

For : METHOD FOR REGULATING PHAGOCYTOSIS

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to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005

(Date of Deposit)

Andrea L. Colby - Reg. No. 30,194

(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

March 25, 2005

(Date of Signature)

Commissioner for Patents
Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER AND AMENDMENT

Dear Sir:

This Letter respectfully transmits the attached Request for Continued Prosecution, Petition for Extension of Time, Petition to Change Inventorship, the accompanying Assignment and Supplemental Declaration and an Information Disclosure Statement, Form PTO-1449 and accompanying references.

Amendments to the Specification being on page 2 of this paper.

Listing of the Claims begin on page 3 of this paper.

Remarks/Arguments begin on page 6 of this paper.

Amendments to the Specification:

Please insert the following paragraph at page 1, line 1 of the Specification:

This application is a nonprovisional patent application based upon provisional patent application U.S. Serial No. 60/069,797, filed December 16, 1997.

Listing of Claims:

- 1-22. (cancelled)
23. (cancelled)
24. (previously presented) A method of decreasing phagocytosis or ICAM-1 expression in a mammalian cell in need thereof, comprising contacting the cell with a therapeutically phagocytosis- or ICAM-1 decreasing effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
25. (cancelled)
- 26-27. (cancelled)
28. (original) The method of claim 24, wherein the agent inhibits the PAR-2 pathway.
29. (original) The method of claim 24, wherein the agent is selected from the group consisting of a soybean derivative and a serine protease inhibitor.
30. (previously presented) The method of claim 29, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.
31. (original) The method of claim 23 or 24, wherein the mammalian cell is a PAR-2-expressing cell.
32. (original) The method of claim 31, wherein the mammalian cell is selected from the group consisting of a keratinocyte, a fibroblast, and a professional phagocyte.
33. (original) The method of claim 32, wherein the mammalian cell is a keratinocyte.
34. (original) The method of claim 32, wherein the mammalian cell is a fibroblast.
35. (original) The method of claim 32, wherein the mammalian cell is a professional phagocyte.

36. (original) The method of claim 23 or 24, wherein the mammalian cell is a human cell.
37. (cancelled)
38. (previously presented) A method of treating a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administered to the cells in need thereof a phagocytosis- or ICAM-1-decreasing therapeutically effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
39. (cancelled)
40. (previously presented) A method of preventing a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells in need thereof a prophylatically phagocytosis- or ICAM-1 decreasing effective amount of soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
41. (cancelled)
42. (cancelled)
43. (cancelled)
44. (original) The method of claim 38 or 40, wherein the agent inhibits the PAR-2 pathway.
45. (previously presented) The method of claim 38 or 40, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.

46. (previously presented) The method of claim 45, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.
47. (original) The method of claim 37, 38, 39 or 40, wherein the appropriate cells are PAR-2-expressing cells.
48. (cancelled)
49. (cancelled)
50. (cancelled)
51. (cancelled)
52. (cancelled)
53. (cancelled)
54. (cancelled)
55. (cancelled)
56. (cancelled)
57. (cancelled)
58. (original) The method of claim 37, 38, 39 or 40, wherein the mammal is a human.
- 59-74. (cancelled)

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et al., Kosaka and Katsumi. As has been noted on several occasions during the course of the prosecution of the above-captioned patent application, soy products containing soy trypsin inhibitor activity were well-known to be dangerous for human ingestion. [See Declaration of Katharine Martin filed March 7, 2002] Soy products containing such activity can cause, for example, gastric distress [Martin Declaration, ¶4], morphological alterations of small intestinal epithelium in calves [Martin Declaration, ¶5] and pancreatic enlargement [Martin Declaration, ¶5].

Thus, whether or not Limkatrul et al., Kosaka or Katsumi indicated that the soybean milk protein administered to the mice in Limkatrul's study contained soy trypsin inhibitory activity, those of ordinary skill in the art would not have expected to be able to administer soybean milk protein containing soy trypsin inhibitory activity to a human being.

Furthermore, Kosaka neither suggests nor describes the claimed method of using soy products. Kosaka merely refers to the use of papain, an enzyme found in papaya, in combination with citric acid, for therapeutic effects on diseases of the circulatory and digestive systems. Kosaka does not teach or suggest topical formulations or applications nor does it recognize the use of soy products for phagocytosis. The Final Rejection states, with respect to Kosaka, that "...it is known that tofu contains soybeans. Tofu is eaten by humans as a food source. Thus, if tofu can be eaten by a human so can soybean milk." [Final Rejection, p.3] While applicants recognize that tofu is eaten as a food source, tofu is another soy product that is **processed and cooked prior to eating** such that the soy trypsin inhibitory activity is removed from the food. Soybean milk that is intended for human consumption is also processed to remove the dangerous STI activity prior to ingestion. These soy products are distinguishable from the compositions and methods of applicants' invention which **do** contain soy trypsin inhibitory activity. Thus, Kosaka neither suggests nor describes the methods of applicants' invention.

While Katsumi refers to the use of soybean milk as a "cosmetic" or as a preventative for chapped skin or itching, nowhere does it suggest or describe the use of non-denatured soy products containing soy trypsin inhibitory activity for increasing or decreasing phagocytosis.

Applicants therefore respectfully request reconsideration of the rejections of claims 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 102 as being anticipated by Limkatrul et al., Kosaka and Katsumi and under 35 U.S.C 103 in view of Limkatrul taken with Kosaka or Katsumi.

The Final Rejection further rejected claims 24, 28-36, 38, 40, 44-47 and 58 provisionally under 35 U.S.C. 102(e) as being anticipated by copending patent application Serial No. 09/110,409 and under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of U.S. Patent Application Serial No. 9/110/409. Should claims become granted in the copending patent application, applicants will address the foregoing provisional rejections.

Applicants respectfully request correction of the claim of the benefit of priority with respect to the abovementioned provisional patent application, addition of Michael Costanzo to the inventorship of the above-captioned patent application and reconsideration of the rejections set forth in the Final Rejection of October 25, 2004. An early allowance is earnestly solicited.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and
Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
Dated: March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Seiberg, et al

Serial No.: 09/206,249

Art Unit: 1651

Filed : December 7, 1998

Examiner: Meller

For : METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being faxed to:
Commissioner for Patents, Washington, DC 20231 on

March 25, 2005

(Date of Deposit)

Andrea L. Colby - Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

March 25, 2005

(Date of Signature)

Commissioner For Patents
Washington, D.C. 20231

PETITION FOR EXTENSION OF TIME
AND AUTHORIZATION TO CHARGE
DEPOSIT ACCOUNT THEREFOR

Dear Sir:

Applicants petition the Commissioner of Patents and Trademarks to extend the time for response to the Office Action dated October 25, 2004 for two(2) months from January 25, 2005 to March 25, 2005. An Amendment responding to the aforesaid Office Action is being filed concurrently herewith.

Please charge Deposit Account No. 10-0750/JBP0438/ALC in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby
Reg. No. 30,194
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
DATE: March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Seiberg, et al

Serial No.: 09/206,249

Art Unit: 1651

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(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

March 25, 2005

(Date of Signature)

Commissioner For Patents
Washington, D.C. 20231

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Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby
Reg. No. 30,194
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
DATE: March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Seiberg, et al
Serial No.: 09/206,249 Art Unit: 1651
Filed : December 7, 1998 Examiner: Meller
For : METHOD FOR REGULATING PHAGOCYTOSIS

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Commissioner for Patents, Washington, DC 20231 on

March 25, 2005
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Andrea L. Colby - Reg. No. 30,194
(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/
(Signature)

March 25, 2005
(Date of Signature)

Commissioner For Patents
Washington, D.C. 20231

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Please charge Deposit Account No. 10-0750/JBP0438/ALC in the name of Johnson & Johnson for the cost of filing this Petition. Three copies of this Petition are enclosed.

Respectfully submitted,

/Andrea L. Colby/

Andrea L. Colby
Reg. No. 30,194
Attorney for Applicant(s)

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
DATE: March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miri Seiberg, et al.
Serial No.: 09/206,249 Art Unit: 1651
Filed : July 6, 1998 Examiner: M. Meller
For : METHOD FOR REGULATING PHAGOCYTOSIS

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope addressed
to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005

(Date of Deposit)

Andrea L. Colby - Reg. No. 30,194

(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

March 25, 2005

(Date of Signature)

Assistant Commissioner for Patents
Washington, D.C. 20231

PETITION, AMENDMENT, STATEMENT OF ASSIGNEE AND FEE TO CORRECT
INVENTORSHIP UNDER 37 CFR §1.48(a)

Dear Sir:

Applicants hereby petition to correct the inventorship in
the above-identified patent application.

Please add the following inventor: **Michael J. Costanzo** in
the above-identified patent application.

The following documents are attached hereto:

- (1) a Statement of Facts verified by the originally named inventors establishing when the error without deceptive intention was discovered and how it occurred; and
- (2) a Declaration by each actual inventor.

Johnson & Johnson Consumer Companies, Inc., Grandview Road, Skillman, NJ 08558 hereby consents to the correction of inventorship filed herewith.

The Assignment for the above-identified patent application was submitted to the Patent and Trademark Office on May 3, 1999 (Reel No. 9933710) to Johnson & Johnson Consumer Companies, Inc., a copy of which is attached hereto.

Please charge the fee set forth in 37 CFR §1.17(h) to Deposit Account No.: 10-0750/JBP438/ALC. A triplicate copy of this sheet is attached hereto.

Respectfully submitted,

By: /Andrea L. Colby/
Andrea L. Colby
(Attorney for Applicants and
Assistant Secretary,
Johnson & Johnson
Consumer Companies, Inc.)
Reg. No. 30,194

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
Dated: March 25, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Miri Seiberg et al. Confirmation No.: 5255
Serial No. : 09/206,249 Art Unit: 1654
Filed : December 7, 1998 Examiner: Michael V. Meller
For : Compositions and Methods for Regulating
Phagocytosis and ICAM-1 Expression

I hereby certify that this correspondence is being deposited with the
United States Postal Service as first class mail in an envelope addressed
to: Commissioner For Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

March 25, 2005

(Date of Deposit)

Andrea L. Colby, Reg. No. 30,194

(Name of applicant, assignee, or Registered Representative)

/Andrea L. Colby/

(Signature)

March 25, 2005

(Date of Signature)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FIFTH SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This copy is supplemental to the Information Disclosure
Statement mailed on September 1, 2004.

Pursuant to 37 C.F.R. §1.56 and in accordance with 37
C.F.R. §§1.97-1.98, information relating to the above-
identified application is hereby disclosed. Inclusion of
information in this statement is not to be construed as an
admission that this information is material as that term is
defined in 37 C.F.R. §1.56(b).

Applicant(s) reserve(s) the right to establish the
patentability of the claimed invention over any of the
information provided herewith, and/or to prove that this

information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist.

☒ In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified national application (other than a continued prosecution application under §1.53(d)), within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of a request for continued examination under §1.114, no additional fee is required.

☐ In accordance with §1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, or an action that otherwise closes prosecution and that it is accompanied by one of:

- ☐ Statement in Accordance with §1.97(e) (attached); or
- ☐ Please charge Deposit Account No. 10-0750/ / the fee of \$180.00 as set forth in §1.17(p).

☐ In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee. Applicant(s) hereby petition(s) for consideration of this Information Disclosure Statement. Included are: Statement in Accordance with §1.97(e) as set forth below and the fee of \$180.00 as set forth in §1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

☐ Copies of only foreign patent documents and non-patent literature are enclosed in accordance with 37 CFR 1.98 (a)(2). (The U.S. patents and each U.S. patent application publication listed on the attached Form PTO-1449 are not enclosed because this U.S. patent application was filed after June 30, 2003 or this international application has entered the national stage under 35 USC §371 after June 30, 2003 (see USPTO waiver of requirement under 37 CFR 1.98 (a)(2)(i)).

☒ There are no listed references which are not in the English language.

☐ The relevance of those listed references which are not in the English language is as follows:

☐ Attached are copies of search report(s) from corresponding patent application(s), which are listed on the attached Submission Under MPEP 609 D.

☐ Attached are the following non-published pending patent applications which may be deemed relevant, which are listed on the attached Submission Under MPEP 609 D.

Please charge any deficiency or credit any overpayment to Deposit Account No. 10-0750/JBP0438/ALC. This form is submitted in triplicate.

Respectfully submitted,

/Andrea L. Colby/
Andrea L. Colby
Reg. No. 30,194
Attorney for Applicants

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2793
DATED: March 25, 2005

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U. S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS, SEND TO:** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Miri Seiberg, et al.
Serial No.: 09/206,249 Art Unit: 1651
Filed : December 7, 1998 Examiner: M. Meller
For : METHOD FOR REGULATING PHAGOCYTOSIS

Assistant Commissioner for Patents
Washington, D.C. 20231

STATEMENT OF FACTS UNDER 37 CFR §1.48(a)

Dear Sir:

We, Miri Seiberg, Stanley S. Shapiro, and Magdalena Eisinger, the originally-named inventors to the above-mentioned application, declare and say:

During the preparation of the above-identified patent application, Michael J. Costanzo provided Andrea Colby, the attorney for Applicants, with some facts that suggested that he should be included as an inventor to the above-referenced application.

At the time that this application was filed, the Applicants inadvertently and without deceptive intent failed to include Mr. Costanzo as an inventor.

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these

statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application and any patent issued thereon.

Date: 1/6/05 2004

Miri Seiberg

Date: 1/7/05 2004

Stanley S. Shapiro

Date: 1/6/05 2004

Magdalena Eisinger

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (10-00)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

<p align="center">DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)</p> <p><input type="checkbox"/> Declaration Submitted with Initial Filing <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required) OR</p>	Attorney Docket Number	JBP438
	First Named Inventor	Miri Seiberg
	COMPLETE IF KNOWN	
	Application Number	09/206,429
	Filing Date	December 7, 1998
	Group Art Unit	1654
	Examiner Name	Michael V. Meller

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR REGULATING PHAGOCYTOSIS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 12/07/1998 as United States Application Number or PCT International Application Number 09/206,429 and was amended on (MM/DD/YYYY) ☐

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.
60/069797	12/16/1997	

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

☒ Practitioners at Customer Number **000027777** →

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☐ Practitioner(s) named below:
Name Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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City:

State:

ZIP

Country

Telephone:

Fax:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Miri

Family Name
or Surname Seiberg

Inventor's
Signature

Date

Residence: City Princeton

State NJ

Country USA

Citizenship US and Israel

Mailing Address 168 Herrontown Road

City Princeton

State NJ

ZIP 08540

Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Stanley S.

Family Name
or Surname Shapiro

Inventor's
Signature

Date

Residence: City

State NJ

Country USA

Citizenship USA

Mailing Address

City

State NJ

ZIP

Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF THIRD INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Magdalena G.

Family Name
or Surname Eisinger

Inventor's
Signature

Date

Residence: City Demarest

State NJ

Country USA

Citizenship USA

Mailing Address 30 Pine Terrace

City Demarest

State NJ

ZIP 07627

Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF FOURTH INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name (first and middle [if any]) Michael J.		Family Name or Surname Costanzo	
Inventor's Signature		Date:	
Residence: City Ivyland	State PA	Country USA	Citizenship USA
Mailing Address 14 Breckenridge Drive			
City Ivyland	State PA	ZIP 18974	Country USA

Please type a plus sign (+) inside this box ☐

PTO/SB/01 (10-00)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63) <input type="checkbox"/> Declaration Submitted with Initial Filing <input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (Surcharge (37 CFR 1.16(e)) required)	Attorney Docket Number	JBP438
	First Named Inventor	Miri Seiberg
	COMPLETE IF KNOWN	
	Application Number	09/206,429
	Filing Date	December 7, 1998
	Group Art Unit	1654
	Examiner Name	Michael V. Meller

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.
I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

METHODS FOR REGULATING PHAGOCYTOSIS
(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 12/07/1998 as United States Application Number or PCT International Application Number
09/206,249 and was amended on (MM/DD/YYYY) ☐

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

DECLARATION - Utility or Design Patent Application

I hereby claim the benefit under 35 U.S.C. 119(e) of any United States provisional application(s) listed below.

Application Number(s)	Filing Date (MM/DD/YYYY)	
60/069797	12/16/1997	<input type="checkbox"/> Additional provisional application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

I hereby claim the benefit under Title 35, United States Code, § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status
		Patented Patented Patented

I hereby appoint:

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Number Bar Code
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AND

☐ Practitioner(s) named below:
Name Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

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Address:

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Country

Telephone:

Fax:

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Mini

Family Name
or Surname Seiberg

Inventor's
Signature

Date

Residence: City Princeton

State NJ

Country USA

Citizenship US and Israel

Mailing Address 168 Herrontown Road

City Princeton

State NJ

ZIP 08540

Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SECOND INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Stanley S.

Family Name
or Surname Shapiro

Inventor's
Signature

Date

Residence: City

State NJ

Country USA

Citizenship USA

Mailing Address

City

State NJ

ZIP

Country USA

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF THIRD INVENTOR:

☐ A petition has been filed for this unsigned inventor

Given Name
(first and middle [if any]) Magdalena G.

Family Name
or Surname Eisinger

Inventor's
Signature

Date

Residence: City Demarest

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF FOURTH INVENTOR:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any)) Michael J.		Family Name or Surname Costanzo	
Inventor's Signature <i>Michael J. Costanzo</i>		Date: October 12, 2004	
Residence: City Ivyland	State PA	Country USA	Citizenship USA
Mailing Address 14 Breckenridge Drive			
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